IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs/Counter-Defendants, v. JOHNSON & JOHNSON and CORDIS CORPORATION Defendants/ Counter-Plaintiffs.	C.A. No. 07-333-SLR C.A. No. 07-348-SLR C.A. No. 07-409-SLR **REDACTED PUBLIC VERSION**
BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs/Counter-Defendants, v. JOHNSON & JOHNSON, CORDIS CORPORATION, and WYETH Defendants/Counter-Plaintiffs.	C.A. No. 07-765-SLR

RESPONSE BRIEF OF JOHNSON & JOHNSON, CORDIS CORPORATION, AND WYETH IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF U.S. PATENT NOS. 7,217,286, 7,223,286, 7,229,473, AND 7,300,662 UNDER 35 U.S.C. § 112

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INTRODUCTION

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively, "BSC") seek summary judgment that all sixty-one asserted claims in the four patents-in-suit are invalid for failure to satisfy the enablement, written description, and definiteness requirements.[1] But written description is an issue of fact, and while enablement and indefiniteness are issues of law, they depend in this case upon the resolution of underlying issues of fact. These crucial factual issues here are hotly disputed, and the patentees (collectively "Cordis") have submitted expert declarations, deposition testimony, and other evidence showing the existence of these disputes. BSC's motion for summary judgment must therefore be denied, because BSC simply ignores the extensive evidence that contradicts its arguments and instead relies upon snippets of evidence and attorney argument.

BSC compounds this error by assuming that the inferences to be drawn from this fragmentary evidence should be drawn in BSC's favor rather than in favor of the non-moving parties. Equally fatal to BSC's motion is its failure to address the state of the art – what was known to skilled artisans at the time that the patent application was filed. Because a patent specification need not repeat what the person of ordinary skill already knows, the state of the art is critically important in evaluating whether a patent specification complies with the enablement and written description requirements of Section 112.

A crucial factual dispute here is whether the specification, in light of what was known in the art at the time of filing, would have enabled one of ordinary skill in the art to practice the

[1] BSC also seeks summary judgment of invalidity on Claims 1, 2, 5, 6, 40, 41, 44, 47 and 48 of U.S. Patent No. 7,223,286. However, as set forth in pp. 17-18 of Defendants/Counter-Plaintiffs Johnson & Johnson and Cordis Corporation's Opposition to Plaintiff's Motion for Summary Judgment of Non-Infringement of the Asserted Claims of the '7286, '3286 and '473 patents-in-suit, BSC's motion for summary judgment regarding the validity of these claims is not justiciable and should be denied as moot.

claimed invention without undue experimentation. BSC says "no," because a person of ordinary skill would not have known about sirolimus analogs or have been able to determine, through routine experimentation, which sirolimus analogs would be suitable for use in the claimed invention. But BSC relies largely on attorney argument and fails to mention the deposition testimony of BSC's own expert.

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BSC's moving papers are notable for the absence of even one declaration – from an expert, a person of ordinary skill in the art, or any other fact witness. Rather than relying upon such evidence, BSC asks that the Court declare the patents-in-suit invalid based largely upon attorney argument. The one fact that BSC emphasizes – that securing FDA approval for the Xience stent took years – is irrelevant, because a patent can satisfy the enablement, written description, and definiteness requirements without providing the data needed to secure FDA approval of an infringing product.

NATURE AND STAGE OF THE PROCEEDINGS

BSC brought these declaratory judgment patent cases. Johnson & Johnson and Cordis Corporation counterclaimed for infringement of three of the patents-in-suit by BSC's Promus Everolimus-Eluting Coronary Stent System (the "Promus stent"). Johnson & Johnson, Cordis Corporation and Wyeth counterclaimed for infringement of a fourth patent-in-suit.[2] The Court has scheduled a claim construction and summary judgment hearing on October 30, 2009, a pretrial conference on January 14, 2010, and a trial beginning February 4, 2010.

[2] The four patents at issue in this case are U.S. Patent 7,223,286 (the "'3286 patent"), U.S. Patent 7,217,286 (the "'7286 patent"), U.S. Patent 7,229,473 (the "'473 patent"), and U.S. Patent 7,300,662 (the "'662 patent"). Wyeth is only a party in the case involving the latter patent.

SUMMARY OF THE ARGUMENT

1. BSC argues that the patents-in-suit are invalid for lack of enablement because the specification does not identify particular rapamycin analogs. According to BSC, a person of skill in the art could therefore not make and use the invention without undue experimentation.

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Moreover, Cordis has submitted expert declarations which state that the suitability of particular analogs could readily have been determined using nothing more than the routine tests employed by the inventors and disclosed in the patent specification. There is also uncontradicted evidence that the molecular structure of rapamycin was well known as of the filing date, as was its method of action and its biological activity. Using this information, a person of ordinary skill could have conducted routine tests to identify analogs that performed similarly to the parent sirolimus compound.

Other important factors that the Federal Circuit has repeatedly said bear on the analysis of whether a patent complies with the enablement requirement include the breadth of the claim, the predictability of the art, the state of the art, the quantity of experimentation needed, and the amount of direction or guidance provided by the specification. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). BSC argues, for example, that the claims are directed to a very broad "class of compounds" such as antibiotics because they could theoretically encompass the use of a large number of rapamycin analogs. However, Cordis has submitted expert declarations pointing out that sirolimus is a single compound, whose structure was published in the scientific literature as of the filing date and whose biological activity had been thoroughly investigated. Its macrocyclic lactone or triene analogs were compounds with essentially the same structure and

similar biological activity, and would have been easily identifiable by a person of ordinary skill as of the time of filing.

Cordis believes that the jury will conclude, based upon this evidence, that the enablement requirement was satisfied here. But at a minimum, this evidence creates material issues of disputed fact that require that BSC's motion for summary judgment be denied.

2. BSC also argues that the patents-in-suit are invalid for failure to satisfy the written description requirement because the specification does not adequately convey that the inventors had possession of the concept of rapamycin analogs. But whether BSC is correct or not turns, once again, on disputed fact questions. The specification provides clear guidance as to the specific properties required for the claimed analogs. Cordis has submitted an expert declaration concluding that a person of ordinary skill, having read these disclosures in the specification in light of the preexisting scientific knowledge, would have understood that the inventors had possession of the claimed analogs. This creates a fact dispute that requires a trial.

3. On indefiniteness, BSC argues that the patents-in-suit are invalid because the metes and bounds of the claimed "macrocyclic triene analog" or "macrocyclic lactone analog" of rapamycin cannot be defined. But these claim terms are certainly susceptible to being construed: indeed, both sides have proposed constructions. Under either side's construction, a person of ordinary skill could determine whether a given compound was covered by the claims or not, according to the declaration of Professor David Sabatini of MIT which accompanies this brief. To be sure, BSC may dispute this point at trial, but the underlying fact question needs to be resolved by the jury.

FACTUAL BACKGROUND

The '662 Patent

1. The Disclosure in the '662 Patent Regarding the Use of Rapamycin Analogs

The '662 patent claims a stent which contains, among other things, "rapamycin or a macrocyclic triene[3] analog thereof that binds FKBP12." (*Appendix to the Response Brief of Johnson & Johnson, Cordis Corporation, and Wyeth in Opposition to Plaintiffs' Motion for Summary Judgment of Invalidity of U.S. Patent Nos. 7,217,286, 7,223,286, 7,229,473, and 7,300,662 Under 35 U.S.C. § 112* (hereafter "A") at A1372, Claim 1) The '662 patent specification explained that:

> Rapamycin used in this context includes rapamycin and all analogs, derivatives[4] and congeners[5] that bind FKBP12 and possess the same pharmacologic properties as rapamycin.

(A1367, Col. 7, lns. 29-32) "Sirolimus" is another name for the parent rapamycin compound.

As of the January 2001 filing date, sirolimus was a well-characterized compound that had been discussed extensively in the scientific literature. Its structure was known. (A7-A8, ¶17) Its biological activity had been thoroughly studied. (A8, ¶¶18-20) Sirolimus worked by first binding to a material called FKBP12 and then binding to an enzyme called TOR, which regulates cell reproduction. (A8, ¶18) TOR was inactivated once it was bound to sirolimus. (*Id.*) By the

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January 2001 filing date, the binding interaction between sirolimus and FKBP12, as well as between sirolimus and TOR, had been carefully investigated. Even the respective binding regions of the three molecules had been determined and published in the scientific literature. (A8, ¶20)

The '662 patent specification described the particular attributes of sirolimus that led to the desired results in a drug eluting stent. While all of the details of the mechanism of action were "still being elucidated," it was known:

> that rapamycin enters cells and binds to a high-affinity cytosolic protein called FKBP12. The complex of rapamycin and FKBP12 in turn binds to and inhibits a phosphoinositide (PI)-3 kinase called the "mammalian Target of Rapamycin" or TOR. TOR is a protein kinase that plays a key role in mediating the downstream signaling events associated with mitogenic growth factors and cytokines in smooth muscle cells and T lymphocytes.

(A1366, Col. 5, ln. 65 to Col. 6, ln. 6) Through the mechanism of first binding to FKBP12, and then to TOR, according to the specification, "[r]apamycin reduces vascular hyperplasia [i.e., the clogging of arteries] by antagonizing smooth muscle proliferation in response to mitogenic signals that are released during angioplasty." (A1366, Col. 5, lns. 52-53) Sirolimus was the inventors' preferred embodiment (A1371, Col. 16, lns. 25-27), and it had been used on the Cypher® drug eluting stent that achieved outstanding results in humans, according to the data in Table 5 of the specification. (A1368-A1369, Table 5) As a result, in selecting an analog for use in the invention, a person of ordinary skill would have to look for an analog having binding regions and binding interactions that were as close as possible to the original sirolimus compound. (A8-A9, ¶21) These binding regions are located in the macrocyclic ring of the sirolimus molecule (A8, ¶20), which is why the patents-in-suit require a "macrocyclic triene" or a "macrocyclic lactone" analog of rapamycin where the macrocyclic ring is left intact.

2. Known Analogs As of the Filing Date of the '662 Patent

As of the January 2001 filing date, there were identified, known molecules that were analogs of sirolimus that would bind FKBP12, as described in the specification. (A1367, Col. 7, lns. 29-32.)

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These sirolimus analogs were no secret.

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To work with a given sirolimus analog, one simply needed to approach the company that had already synthesized it and secure a sample. Wyeth, for example, had a stable of sirolimus analogs, and made them available to third parties for study. (A2680-A2697) Indeed, the scientific literature describes some of the resultant research results, crediting Wyeth as the source of the sirolimus analog in question. *See* Taylor *et al.*, Quantitative analysis of sirolimus (Rapamycin) in blood by high-performance liquid chomatography-electrospray tandem mass spectrometry, J. Chromatogr. B 718 at 252 (1998) ("Sirolimus and the sirolimus analog, 32-O-desmethoxysirolimus (internal standard) were a gift from Wyeth-Ayerst Research") (A1763-A1769).

Guidant Corporation, a predecessor of Abbott Laboratories and the developer of the accused Promus stent, obtained its sirolimus analog (everolimus) from Novartis Corporation, which made it.

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Novartis also supplied sirolimus analogs to other third party investigators, as is acknowledged in the scientific literature from before the January 2001 filing date. *See* Christians *et al.*, Automated, fast and sensitive quantification of drugs in blood by liquid chromatograph-mass spectrometry with on-line extraction: immunosuppressants, J. Chromatogr. B 41 at 51 (2000) ("As an alternative to 28,40-O-diacetyl rapamycin, we used 32-desmethoxy rapamycin (Wyeth-Ayerst Research, Pearl River, NY, USA) or 20-O-(3-hydroxypropyl) rapamycin (Novartis Pharma, Basel, Switzerland) with similar results") (A1581-A1593).

3. The Ability of a Person of Ordinary Skill to Determine Whether an Analog Bound FKBP12 and TOR.

According to Professor Sabatini, there would have been no need to perform tests to determine whether many of the known analogs could bind FKBP12 and TOR; a person of ordinary skill could simply have consulted the published literature to find the answer. (A9-A10, ¶23) However, if the person of ordinary skill chose to work with an analog for which binding results were not reported, it would have been a routine matter to test the analog and determine if it could bind to FKBP12 and TOR. (A9-A11, ¶23-26)

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Performing the rotamase assay was well within the ability of a person of ordinary skill.

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Again, because all of this information was already known to the person of ordinary skill in the art, it did not need to be repeated in the specification: "a patentee preferably omits from the disclosure any routine technology that is well known at the time of application." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004).

4. Employing a Suitable Analog on a Stent for Use in Humans

For purposes of the present motion, BSC focuses on the selection of suitable rapamycin analogs and apparently does not question the ability of a person of skill in the art to have put an

analog (once identified) on a stent and then test the resulting drug eluting stent. This is in accord with the evidence. Cordis experts have opined that a person of ordinary skill in the art could follow the teachings in the specification to place the drug on a stent, using one of the polymer carriers suggested. (Mikos Decl. at A24-A27, ¶¶19-26; Rogers Decl. at A39-A44, ¶¶14-23) Prototypes of the drug eluting stent could then be implanted in animals, using the dosages and study protocols described in the patent. Detailed protocols for such testing had been described in the scientific literature. *See, e.g.*, Hårdhammar *et al.*, Reduction in Thrombotic Events With Heparin-Coated Palmaz-Schatz Stents in Normal Porcine Coronary Arteries. *Circulation* 1996; 93:423-430 (A1620-A1627). Table 3 in the patent provides information on the appropriate test animals (pigs and rabbits) and dose ranges to consider. (A1367-A1368) The specification recommends that one employ in humans "the same dose range as studied in animal models" and it suggests that the results in humans may be even better than what is predicted by the animal models. (A1369, Col. 11, lns. 34-42).

The 1997 Patents

The other three patents-in-suit are U.S. Patents 7,223,286, 7,217,286, and 7,229, 473 (collectively, the "1997 patents"). They have a common specification that differs from that of the '662 patent. They also have an earlier effective filing date, April 18, 1997.

1. The Disclosure in the 1997 Patents Regarding the Use of Rapamycin Analogs

The 1997 patents claim stents containing, among other things, "rapamycin or a macrocyclic lactone analog thereof." (*E.g.*, A1277, Claim 1) The specification of the 1997 patents describes the use "[r]apamycin (sirolimus) structural analogs (macrocyclic lactones[6]) and

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inhibitors of cell-cycle progression." (A1276, Col. 6, lns. 2-3; A1258, Col. 6, lns. 4-5; A1295, Col. 6, lns. 5-6)

As of April of 1997, the scientific literature reported the structure of sirolimus, as well as the fact that its biological activity resulted from its ability to bind first to FKBP12 and then to TOR. (A8, ¶18) By the April 1997 filing date, the binding interaction between sirolimus and FKBP12, as well as between sirolimus and TOR, had been thoroughly explored, and the respective binding regions of the three molecules had been determined and published. (A8, ¶19)

2. Known Analogs As of the Filing Date of the 1997 Patents

As of April 18, 1997, a person of ordinary skill in the art would have been aware of at least twenty-five sirolimus analogs which had the exact same macrocyclic lactone ring as the parent compound. These analogs were publicly known, having been described in a prior art publication. (A9, ¶22; A1464-A1507; A1827-A1828) The twenty-five known analogs included everolimus, the drug which BSC now uses on its Promus stent. (A9, ¶22; A1828-A1829)

3. The Ability of a Person of Ordinary Skill to Determine Whether an Analog Bound FKBP12 and TOR

According to Professor Sabatini, a person of ordinary skill would therefore have understood that for a sirolimus analog to have biological activity similar to sirolimus, the analog would need to bind FKBP12 and TOR. (A7-A8, ¶17) The tests that were used to assess whether a given analog bound FKBP12 and TOR had been developed as of April 1997. (A10-A11, ¶25)

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4. Employing a Suitable Analog on a Stent for Use in Humans

For purposes of the 1997 patents, BSC again focuses on the selection of suitable rapamycin analogs and does not question the ability of a person of skill in the art to have made use of an analog in the claimed invention, once the analog was identified. Again, this is in accord with the evidence. Cordis experts have opined that based on the teachings of the 1997 patents and the knowledge of persons of skill in the art, making a stent of the type claimed would have required only routine experimentation. (Mikos Decl. at A11-A16, ¶¶27-39; Rogers Decl. at A44-A45, ¶¶24-27) The specification of the 1997 patents described how to prepare a solution of drug and polymer to coat a stent, and it suggested a number of suitable polymers. (A1276, Col. 6, lns. 32-46; A1258, Col. 6, lns. 34-49; A1295, Col. 6, lns. 35-50) Once drug coated stent prototypes had been built, they could have been tested in animal studies following a protocol described in the scientific literature. *See, e.g.*, Hårdhammar *et al.*, Reduction in Thrombotic Events With Heparin-Coated Palmaz-Schatz Stents in Normal Porcine Coronary Arteries. *Circulation* 1996; 93:423-430) (A1620-A1627).

LEGAL STANDARD FOR SUMMARY JUDGMENT

Summary judgment may not be granted unless "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In determining whether summary judgment is appropriate, the "evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

The trial court's duty at the summary judgment motion stage of the litigation is merely to discern "whether there are disputed material facts"; it does not extend to resolving any such disputes. *SunTiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1333 (Fed. Cir.

1999). If the factual evidence leaves "room for some difference of opinion," the accused infringer has failed to meet the clear and convincing standard at summary judgment. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575 (Fed. Cir. 1987). Moreover, in considering summary judgment, a District Court "can and should take into account expert testimony, which may resolve or keep open certain questions of fact." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 427 (2007).

ARGUMENT

Because the specification of U.S. Patent 7,300,662 (the "'662 patent") differs from the specification for the other three patents-in-suit, the written description, enablement, and definiteness questions are different for it versus the other three patents. In the discussion below, the '662 patent is addressed first, followed by an analysis of the other three patents.

I. SUMMARY JUDGMENT OF INVALIDITY CANNOT BE ENTERED FOR THE '662 PATENT, BECAUSE BSC'S INVALIDITY ARGUMENTS INVOLVE HOTLY DISPUTED ISSUES OF FACT.

A. BSC's Enablement Arguments Involve Disputed Factual Issues.

BSC argues that the '662 patent is invalid because the claims contemplate the use of "rapamycin or a macrocyclic triene analog thereof" and "[n]o Rapamycin Analog is disclosed in any figure, diagram chemical formula, or chemical structure of the specification." (D.I. 257 at 28).[7] As a result, according to BSC, "the asserted claims of the '662 patent are "invalid for nonenablement." D.I. 257 at 29.

[7] All citations to the docket refer to Civil Action No. 1:07-CV-333-SLR unless otherwise specified. D.I. 257 is *BSC's Opening Brief in Support of Its Motion for Summary Judgment of Invalidity of U.S. Patent Nos. 7,217,286, 7,223,286, 7,229,473, and 7,300,662 Under 35 U.S.C. § 112* (Sept. 16, 2009.), and was also filed as D.I. 253 in 1:07-348-SLR, D.I. 258 in 1:07-409-SLR, and D.I. 259 in 1:07-SLR-765.

BSC is certainly entitled to make these arguments at trial, but summary judgment is plainly inappropriate on this record because BSC's enablement arguments turn on numerous disputed issues of fact.

1. The Law of Enablement

The enablement requirement is satisfied if the patent would have taught "those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004) (citations omitted). Though "the ultimate determination of whether one skilled in the art could make and use the claimed invention without undue experimentation is a legal one, it is based on underlying findings of fact." *Warner-Lambert Co. v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326, 1337 (Fed. Cir. 2005) (reversing summary judgment on enablement where expert testimony regarding undue experimentation raised a genuine issue of fact precluding summary judgment.). *See also MEMC Electronic Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 248 F. App'x 199, 203-204 (Fed. Cir. 2007) (finding declarations of patentee's witnesses created genuine issues of material fact on enablement and precluded summary judgment). BSC has the burden of "clearly and convincingly proving facts showing that the claims were not enabled." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003).

To satisfy the enablement requirement, the "patent need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). Thus, the extent to which a patent enables its claims is based upon "that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation." *Nat'l Recovery Technologies, Inc. v. Magnetic Separation Systems, Inc.*, 166 F.3d 1190, 1166 (Fed. Cir. 1999). *See also Amgen Inc. v. Hoescht*

Marion Roussel Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003) ("The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if given what they already know, the specification teaches those in the art enough that they can make and use the invention without undue experimentation"). In other words, one may "resort to material outside the specification" for known aspects of the claimed invention "because it make no sense to encumber the specification of a patent with all the knowledge of the past concerning how to make and use the claimed invention" *Atmel Corp. v. Info Storage Devices Inc.*, 198 F.3d 1374, 1382 (Fed. Cir. 1999).

Here, there is a factual dispute as to whether a person of ordinary skill, as of the January 2001 filing date, could use a "macrocyclic triene analog" of sirolimus in the claimed invention, and do so without undue experimentation. Cordis has submitted expert declarations opining that undue experimentation would not be required, and this forecloses summary judgment. (Sabatini Decl. at A7, ¶16; Mikos Decl. at A21, ¶10; Rogers Decl. at A37, ¶9) The nature of the factual dispute here is described in greater detail below.

2. Based Upon the Teachings of the '662 Patent Specification, a Person of Ordinary Skill Could Have Identified Suitable Sirolimus Analogs From Among the Analogs That Were Publicly Known.

Although BSC complains that "[n]o Rapamycin Analog is disclosed in any figure, diagram, chemical formula, or chemical structure of the specification" (D.I. 257 at 28), BSC has simply ignored the fact that a person of ordinary skill would already have known of such analogs as of the patent filing date in January 2001. **REDACTED**

And in connection with one of its other summary judgment motions, BSC itself made the crucial admission that "prior art references discuss rapamycin (and analogs of rapamycin) in detail." *Plaintiffs' Opening Brief in Support of Their Motion for Summary Judgment of Invalidity of the '7286, '3286, and '473 Patents-in-Suit Pursuant to 35 U.S.C. §103* at 10 (September 16, 2009).

There was no need for the inventors to include figures in the specification showing the chemical structure of these compounds, or even to list them by name, because the "person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) As the Federal Circuit has emphasized, "a patent need not teach, and preferably omits, what is well known in the art." *Hybritech,* 802 F.2d at 1385.

BSC argues that *Automotive Technologies Int'l, Inc. v. BMW of North America, Inc.*, 501 F.3d 1274 (Fed. Cir. 2007) is "squarely on point" (D.I. 257 at 15), but that is incorrect. In *Automotive Technologies*, the claims encompassed electronic sensors for side impact in automobiles, but the specification contained no "discussion of the circuitry involved in the electronic side impact sensor" or even a "structure or description of how a person having ordinary skill in the art would make or use an electronic side impact sensor." 501 F.3d at 1283. At the time the patent application was filed, electronic sensors "could not be obtained commercially," and no one had yet solved two thorny technical problems: "how to sense the motion of the mass in order to properly output a stream of data, and how to appropriately process the data." *Id.* at 1284. This case is different because many sirolimus analogs had been identified, described, and characterized in the literature, and thus were known to the person of ordinary skill, when the patent application was filed in January 2001. (A1832; A9, ¶¶22) The many known analogs in this case contrast with the number of known electronic side impact sensors in *Automotive Technologies*: zero.

BSC also complains that the specification did not provide guidance for the design and synthesis of new sirolimus analogs "from the vast universe of candidates." (D.I. 257 at 28) But with existing analogs to choose from, a person of ordinary skill would have had no practical need to design or synthesize a new one. **REDACTED**

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To the extent a person of ordinary skill chose to create a new molecule, however, the guidance from the patent specification and the existing scientific knowledge concerning sirolimus's structure, mechanism of action, binding interactions, and binding regions would have led a person skilled in the art to consider only a narrowly-defined class of compounds: those with the same macrocyclic ring structure as sirolimus and similar biological activity. (A8-A9, ¶21) In any event, analogs designed and synthesized after January 2001 constitute "technology that arises after the date of application," and the "law does not expect an applicant to disclose knowledge invented or developed after the filing date" because such "disclosure would be impossible." *Chiron Corp.*, 363 F.3d at 1254.

BSC's entire argument reflects a fundamental misconception of the nature of the invention in the '662 patent. The invention was neither the discovery of new sirolimus analogs nor the discovery that such analogs could be used therapeutically in preventing restenosis. To the contrary, the invention was a novel drug eluting stent which employed a highly effective, and novel, combination of previously-known elements.[8]

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[8] This case is thus very different from *In re '318 Patent Infringement Litigation*, __F.3d__ (Fed. Cir. 2009), where the Court held that a claim to a method of treating Alzheimer's disease by administering galanthamine failed to satisfy the enablement requirement of § 112. The Court based its decision, in large part, on the lack of utility of the claimed invention. Quoting *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999), the Court explained, "If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement." Neither the patent specification nor the prior art in that case provided any indication that the drug could be used to treat Alzheimer's disease and that the claimed invention therefore had utility. *In re '318 Patent Infringement Litigation*, Nos. 2008-1594, 2009-1070, 2009-1088, 2009 WL 3051755, at *5-*6 (Fed. Cir. Sep. 25, 2009). Here, by contrast, it was already known from the prior art that "rapamycin" and "rapamycin analogs" had utility in treating or preventing restenosis, (*See, e.g.,* U.S. Patent Nos. 5,516,781; 5,563,146; 5,665,728; 5,362,718), and the invention was the combination of this drug and other elements in a stent design that achieved remarkable and unexpected results.

3. After Identifying a Sirolimus Analog, the Person of Ordinary Skill Could Obtain the Analog and Test It Using a Routine Assay.

There is a factual dispute here as to whether a person of skill in the art would have had to engage in undue experimentation to determine if a known sirolimus analog was suitable for use in a stent. BSC urges (based entirely on attorney argument) that undue experimentation would be required. But Cordis has now submitted expert declarations opining that the required experimentation would merely have been routine as of the January 2001 filing date.

Specifically, to identify a sirolimus analog that could be employed in the claimed invention, a person of ordinary skill would simply look for a compound with the same mechanism of action as sirolimus and similar biological activity. As discussed above, many sirolimus compounds were already known and were readily available from their respective makers. Once an analog was in hand, its properties could (in many cases) be found in the literature. Alternatively, the analog could be tested – using routine tests – to determine if it had biological activity that was similar to sirolimus. (A10-A11, ¶¶24-26; A1833)

BSC disputes these facts. Summary judgment is therefore foreclosed by "the highly factual issue of whether, under the circumstances, more than routine experimentation" is "needed to make the invention work." *Northpoint Technology, Ltd. v. MDS America, Inc.*, 413 F.3d 1301, 1310 (Fed. Cir. 2005).

4. After Initial Laboratory Testing, the Person of Ordinary Skill Could Have Put the Analog on a Stent and Performed Additional Routine Tests to Assess Stent Performance and Select a Dosage.

If a sirolimus analog performed well in initial testing of biological activity, it could be tested further. A person of ordinary skill in the art could follow the teachings in the specification to place the drug on a stent, using one of the polymers suggested and employing the recommended coating thicknesses. (A1371, Col. 16, lns. 32-51) BSC does not appear to dispute

the ability of a person of ordinary skill to do so. If BSC does dispute this, that presents yet another factual dispute, given the contrary views articulated in the declarations of Cordis's experts. (Mikos Decl. at A24-A27, ¶¶19-26; Rogers Decl. at A39-A44, ¶¶14-23)

Prototypes of the drug eluting stent could then be implanted in animals, using the study protocols described in the patent and in the scientific literature. Table 3 in the patent provides information on dose ranges to consider. (A1367-A13668, Table 3) The specification recommends that one employ in humans "the same dose range as studied in animal models" and it suggests that the results in humans may be even better than what is predicted by the animal models. (A1369, Col. 11, lns. 34-42)

The "fact that some experimentation is necessary" to determine an optimum dose "does not preclude enablement; what is required is that the amount of experimentation must not be duly extensive." *Chiron Corp.*, 363 F.3d at 1253 (citations and internal quotation marks omitted).

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A pharmacologist either routinely performed dose response studies herself or had ready access to individuals who could do so. *See United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988) (specification is enabling in part because those skilled in the art "would know how to conduct a dose response study" to determine the appropriate amounts to be used). As averred in the declarations of Cordis's experts, this sort of experimentation would have been routine. (Mikos Decl. at A24-A25, ¶¶19-20; Rogers Decl. at A42-A43, ¶20)

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5. Application of the *Wands* Factors Is Fact-Intensive.

BSC refers (D.I. 257 at 18-21) to the eight factors described in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), as bearing on whether the disclosure in a specification was enabling. These *Wands* factors include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* As the mere recitation of these factors indicates, evaluating them is highly fact intensive. Indeed, the *Wands* decision itself emphasized that "[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Id.*

Application of the *Wands* factors is dependent on the particular circumstances in a given case. In fact, "all of the [*Wands*] factors need not be reviewed when determining whether a disclosure is enabling." *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999) (citing *Amgen,* 927 F.2d at 1213 (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.")).

While both sides agree that the relative skill of those in the art was very high, the application of the other *Wands* factors in this case is vigorously disputed. The evidence discussed above shows that there are factual disputes concerning such *Wands* factors as the quantity of experimentation necessary, the amount of direction or guidance presented, the nature of the invention, the state of the prior art, the predictability or unpredictability of the art, and the breadth of the claims.

6. The Effort Expended by Abbott to Commercialize Its Xience Stent Is Not Relevant to the Enablement Inquiry.

BSC argues that Abbott Laboratories (and its predecessor, Guidant Corporation) "conducted prolonged, intensive studies of Everolimus XIENCE prior to launch and commercialization." (D.I. 257 at 13) BSC suggests that because considerable effort was devoted to securing FDA approval for its stent, and then commercializing it, the disclosure of the '662 specification was not enabling. But BSC is measuring the adequacy of the specification against the wrong yardstick. To satisfy the enablement requirement, there is no need for a patent specification to detail how to make "a commercially successful product," much less how to secure FDA approval without considerable effort. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987). All that is required is enough information to permit "one skilled in the art," after reading the specification, to "practice the invention claimed" and do so "without undue experimentation." *Chiron*, 363 F.3d at 1253.

B. BSC's Written Description Arguments Involve Disputed Factual Issues.

Whether a written description requirement even exists, apart from the enablement requirement, is now an open question. The Federal Circuit granted *en banc* review in August 2009 to consider "[w]hether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement." *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, No. 2008-1248, 2009 WL 2573004 at *1 (Fed. Cir. Aug. 21, 2009).[9]

Assuming that there is a separate written description requirement, however, it would normally be satisfied where the enablement requirement was satisfied. After all, if a person of ordinary skill in the art could make and use the claimed invention after reading the specification,

[9] To preserve its rights in the current unsettled state of the law, Cordis maintains that there is no written description requirement separate from the enablement requirement, for the reasons stated in Judge Linn's dissent in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1380-81 (Fed. Cir. 2009).

that typically would indicate that the inventors had possession of the claimed invention. Otherwise, they would not have been able to provide sufficient information to enable a person of ordinary skill to make and use the invention. While admittedly there are rare exceptions where the enablement requirement is satisfied but the written description requirement is not, this case does not present such an exception.

Under current law, whether the written description requirement "is met is a question of fact." *Martek Biosciences Corp. v. Nutrinova, Inc.*, Nos. 2008-1459, 2008-1476, 2009 WL 2780367 at *3 (Fed. Cir. Sept. 3, 2009). Though the Federal Circuit's written description standard has largely emanated from the area of genetic materials, it applies to non-genetic material inventions as well. *See University of Rochester v. G. D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004). However, because "the question of compliance with the description requirement of §112" requires that "each case" be "decided on its own facts," the "precedential value of cases in this area is extremely limited." *Vas-Cath, Inc. v. Mahurkar*, 955 F.2d 1555, 1562 (Fed. Cir. 1991), *quoting In re Driscoll*, 562 F.2d 1245, 1250 (C.C.P.A. 1977). The patents-in-suit are presumed valid, and it is BSC's burden to prove by clear and convincing evidence that the each of the patents-in-suit failed to convey to one of ordinary skill in the art with reasonable clarity that the inventors were in possession of the claimed invention at the time of the filing. *See Invitrogen Corp. v. Clontech Lab., Inc.*, 429 F.3d 1052, 1072 (Fed. Cir. 2005) ("[i]nvalidating a claim requires a showing by clear and convincing evidence that the written description requirement has not been satisfied").

As traditionally formulated, the written description requirement is satisfied where the specification describes the claimed invention and does so "in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." *Lockwood v.*

American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997). The written description requirement may be satisfied by a functional description "if in the knowledge of the art the disclosed function is sufficiently correlated to a particular known structure." *Amgen*, 314 F.3d at 1332. "No length requirement exists for a disclosure to adequately describe an invention." *Falkner v. Inglis*, 448 F.3d 1357, 1365-66 (Fed. Cir. 2006). A patent is written for a person of skill in the art, and that person comes to the patent with the knowledge of what has come before – "[p]laced in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed" the invention. *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (*citing In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995)). In particular, to satisfy the written description requirement, "examples are not necessary to support the adequacy of written description." *Falkner*, 448 F.3d at 1366-67.

BSC argues that the specification does not adequately convey that the inventors had possession of the concept of rapamycin analogs because "there is no disclosure of any figure, diagram, structure, or formula for any actual Rapamycin Analogs to practice the claimed invention." (D.I. 257 at 31) The written description requirement, however, cannot be reduced to a single, simple formulaic test, as BSC argues. It involves a multi-faceted, fact-intensive inquiry and can be satisfied in a variety of ways. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002) is illustrative. The issue in that case was whether the deposit of three nucleotide sequences in a public depository satisfied the written description requirement as to mutated variations of the deposited sequences. The Federal Circuit characterized the required factual inquiry as follows:

> As the deposited sequences are about 850, 850, and 1300 nucleotides long, id. at col. 13, ll. 47-49, there are at least hundreds of subsequences of the

> deposited sequences, an unknown number of which might also meet the claimed hybridization ratio. Moreover, Enzo's expert, Dr. Wetmur, stated that "astronomical" numbers of mutated variations of the deposited sequences also fall within the scope of those claims, and that such broad claim scope is necessary to adequately protect Enzo's invention from copyists who could otherwise make a minor change to the sequence and thereby avoid infringement while still exploiting the benefits of Enzo's invention. The defendants assert that such breadth is fatal to the adequacy of the written description. On the other hand, because the deposited sequences are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art. We regard that question as an issue of fact that is best resolved in remand.

Enzo, 323 F.3d at 966. On remand, the Federal Circuit directed the District Court to "determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants, and mixtures sufficient to demonstrate possession of the generic scope of the claims." *Id.*

In this case, there is a similar fact question: would a person of ordinary skill glean from the written description that the inventors had possession of the generic scope of the claims? In evaluating this issue, it is important to note that the inventors were not claiming to have developed new drugs. Moreover, the claimed genus (rapamycin and macrocyclic triene analogs thereof that bind FKBP 12) was not an unbounded class, such as "anti-proliferative" or "anti-inflammatory" or "non-steroidal" drugs, but rather is tightly limited by structure (rapamycin or a macrocyclic triene analog) and function (e.g., capable of binding FKBP12). The specification included an explicit description of the required mechanism of action. (A1366, Col. 5, ln. 65–Col. 6, ln. 10) In addition, there was a known correlation at the time between the structure of sirolimus and its active analogs and the biological function with respect to restenosis (inhibiting TOR by binding first to FKBP12 and then to TOR) . (A8-A9, ¶21) The regions in the sirolimus

molecule that bound to FKBP12 and TOR had been described in the scientific literature (A8-A9, ¶19-20), and a person of ordinary skill in the art would been guided by that knowledge in choosing an analog for use in the invention. The jury would be entitled to find that the written description requirement was satisfied by a combination of such characteristics.

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The disclosure "required by section 112 is directed to those skilled in the art." *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 926 (Fed. Cir. 1990). Accordingly, "an inventor is not required to describe every detail of his invention," and the "disclosure obligation varies according to the art to which the invention pertains." *Ven-Tel, Inc. v. Hayes Microcomputer Products, Inc.*, 982 F.2d 1527, 1534 (Fed. Cir. 1992).

For example, "in the nineteenth century, use of the word 'automobile' would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, *viz.*, a chassis, an engine, seats, wheels on axles, etc." *University of Rochester*, 358 F.3d at 923. In January 2001, by contrast, an inventor who made an invention involving an automobile could show that he had possession of the "automobile" concept by use of the word "automobile" alone. Providing multiple examples of sirolimus analogs was just as unnecessary in January 2001 as specifying then that an automobile had four wheels and two axles.

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At a minimum, there is a disputed issue of fact as to whether, in January 2001, an abbreviated reference to rapamycin analogs was sufficiently informative in light of the knowledge of sirolimus's structure and function and the known correlation between sirolimus's

configuration and its binding and biological properties. Cordis's experts have opined that a person of ordinary skill would understand from the specification's disclosure, coupled with the preexisting scientific knowledge, that the inventors had possession of the claimed invention. (Sabatini Decl. at A12-A13, ¶¶28-30; Mikos Decl. at A19-A21, ¶¶5-9; Rogers Decl. at A38-A39, ¶¶12-13) That creates a fact question for the jury.

BSC asserts that this case is "strikingly similar" to *University of Rochester*, but that is incorrect. (D.I. 257 at 23) In *University of Rochester*, the "patent's claims all require a COX-2-selective compound, but no COX-2-selective compound is disclosed in the patent, and it is undisputed that there was no pre-existing awareness in the art of any compound having COX-2-selective activity." 358 F.3d at 930. Here, sirolimus was a compound whose structure was described in the scientific literature, as was its mechanism of biological activity. Many sirolimus analogs were known, and their biological activity had been studied and characterized as well.

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Rochester is not "strikingly similar" to this case because there is an enormous difference between many known compounds (this case) and no known compounds (*University of Rochester*).

C. BSC's Indefiniteness Argument Is Meritless.

A claim will be found indefinite only if it "is insolubly ambiguous, and no narrowing construction can properly be adopted." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). However, if the "meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree," the claim is "sufficiently clear to avoid invalidity on indefiniteness grounds." *Id.* The

meaning of the claim terms here is plainly discernable, inasmuch as each side has proposed constructions.

BSC nevertheless argues that the '662 patent claims are invalid because the claim term "macrocyclic triene analog" of rapamycin is indefinite. According to BSC, "macrocyclic triene analog" should be construed to mean "a macrocyclic triene molecule with a structure similar to rapamycin," and so construed, the claim language is not "sufficiently precise to permit a potential competitor to determine whether or not he is infringing." (D.I. 257 at 32) However, a person of ordinary skill – given this proposed construction – could make a judgment about whether a given compound had a "structure similar to rapamycin" – especially in light of the disclosure of the importance of the macrocyclic ring in the specification and the specific properties of sirolimus identified in the specification. (A14, A15, ¶¶32, 34)[10] Technical terms "are not per se indefinite when expressed in qualitative terms without numerical limits." *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1557 (Fed. Cir. 1996). If "the language is as precise as the subject matter permits, the courts can demand no more." *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir.), *cert. dismissed*, 474 U.S. 976 (1985).

The claim language here, as construed under BSC's proposed construction, is at least as precise as the claim language that BSC uses in its own stent patents. For example, BSC obtained U.S. patents which claim drug eluting stents where "the biologically active material is paclitaxel, a derivative of paclitaxel or an analog of paclitaxel." (A1404, Claims 7 & 21) The specification

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of this BSC patent does not elaborate on what is and is not an analog, presumably because a person of ordinary skill in the art would already have understood this concept. (A1400, Col. 24, lns. 17-22) There are other, similar BSC patents.[11]

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what BSC (and the Examiner) deemed as sufficiently definite claiming in BSC's own patents shed light on what is and is not indefinite here. *See Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 822 (Fed. Cir. 1988) (reversing invalidity determination based upon indefiniteness, in part because "[w]ords similar to those used in the Knop claims appear in prior art patents that were of record in the district court, dealing with similar technology").

In any event, for the reasons set forth in the *Markman* briefs, the Court should adopt the construction proposed by Cordis, which is fully supported by the specification and would lay to rest any possible argument as to whether the claims are indefinite. To the extent there is an indefiniteness problem with BSC's proposed construction, as BSC contends, that is a basis for construing this claim term as Cordis suggests, inasmuch as Cordis's proposed construction is a "narrowing construction" that "can properly be adopted." *Exxon Research*, 265 F.3d at 1375. Under Cordis's proposed construction, "macrocyclic triene analog" would be construed to mean

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[11] There are at least three other BSC patents that contain similar claims to analogs without any more fulsome description of what an analog is than is provided in the patents-in-suit. (A1445-A1447, U.S. Patent No. 7,455,875 at Col. 11, lns. 57-12:12 and Claims 6, 19, & 28 (claiming stents where "antiproliferative agent comprises paclitaxel, an analog thereof, a derivative thereof, or a combination thereof"); A1185-A1187, U.S. Patent Nos. 6,861,088 at Col. 11, ln. 52 – Col. 12, ln. 6 and Claims 4, 25, & 31 (claiming stents where "antiproliferative agent comprises paclitaxel, an analog thereof, a derivative thereof, or a combination thereof"); A1420, A1423 U.S. Patent No. 7,356,368 at Col. 17, lns. 14-43 and Claims 7 & 12 (claiming stents where "therapeutic agent is at least one of a penicillin, a cephalosporin, a vancomycin, an aminoglycoside, a quinolone, a polymyxin, an erythromycin, a tetracycline, a chloramphenicol, a clindamycin, a lincomycin, a sulfonamide, or a homolog, an analog, a fragment, a derivative or a pharmaceutically acceptable salt thereof.")

"a compound structurally similar to sirolimus having the same macrocyclic triene ring structure which is capable of inhibiting both the inflammatory response known to occur after arterial injury and stent implantation, as well as the smooth muscle cell hyperproliferative response."

Cordis's proposed construction would cure any possible indefiniteness problem. In his declaration, Professor Sabatini explains how a person of ordinary skill in the art could test a given compound, using routine analytical and experimental techniques, to determine if it was covered by Cordis's proposed construction. (A10-A11, ¶¶24-26) Professor Sabatini notes that the published literature shows that persons of ordinary skill have no problem identifying which compounds have the properties called for in the Cordis construction. (*Id.*)

If BSC concurs in Professor Sabatini's analysis, then there is no indefiniteness problem. *See Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.*, 554 F.3d 1010, 1022 (Fed. Cir. 2009) (finding a claim not indefinite where the patentee submitted a declaration explaining that the ordinarily skilled artisan would have understood the meaning of the claim). However, if BSC disputes his analysis, then there is a fact dispute, underlying the legal question of indefiniteness, and the fact dispute should be submitted to the jury for resolution.

The Federal Circuit has recognized that indefiniteness "is amenable to resolution by the jury where the issues are factual in nature." *BJ Services Co. v. Halliburton Energy Services, Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003) (finding indefiniteness was properly submitted to jury where both parties submitted conflicting expert testimony interpreting claim limitation). *See also Amgen Inc. v. Hoffman-La Roche Ltd.*, Nos. 2009-1020, 2009-1096, 2009 WL 2928763 at *27 (Fed. Cir. Sept. 15, 2009) ("Dr. Lodish's testimony supports a finding that an ordinarily skilled artisan would have understood the boundaries of claim 1 of the '442 patent"). This Court has also repeatedly allowed fact issues underlying indefiniteness to be resolved by the jury. *See*

Dow Chemical Co. v. NOVA Chemicals Corp., 629 F. Supp. 2d 397, 403(D. Del. 2009) ("the Court understands the authority on this issue as allowing, in appropriate circumstances, for the submission an indefiniteness dispute to the jury").[12] Therefore, any factual dispute raised by Professor Sabatini's analysis should be submitted to the jury for resolution.

BSC's description (D.I. 257 at 32-33) of *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244 (Fed. Cir. 2008) is incomplete and misleading. In *Halliburton*, the patentee had "differentiated its invention from the prior art because it was a 'fragile gel.'" 514 F.3d at 1256. However, the construction of "fragile gel" which Halliburton proposed did "not adequately distinguish the fragileness of the invention from disclosed prior art." *Id.* The Federal Circuit could "discern no other construction that can properly be adopted that would render the claims definite." *Id.* In this case, by contrast, the claimed invention was never differentiated from the prior art based upon the inventors' use of sirolimus analogs. Indeed, the invention here had nothing to do with the development of new sirolimus analogs. Instead, the invention made use of sirolimus analogs, including previously known analogs, in a novel combination with other previously known elements. Moreover, unlike the gels in *Halliburton,* as to which there was no objective test for differentiating fragile gels from other gels, in the case of the Cordis patents, objective tests did exist and were referenced in the specification – i.e., whether the analog bound

[12] *See also Telecordia Technologies, Inc. v. Cisco Systems, Inc.*, 592 F. Supp. 2d 727, 739 (D. Del. 2009) ("because the [indefiniteness] inquiry is factual in nature, it is proper to submit it to resolution by the jury"); *Lucent Technologies, Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 243 -244 (D. Del. 2001) ("While recognizing that indefiniteness is a question of law, several courts, including this Court, have also noted that factual questions may underlie the indefiniteness inquiry"); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, Nos. 99-274(SLR), 99-876(SLR), 2004 WL 1305849, *10 (D. Del. 2004) ("in a jury trial, if there are disputed factual issues related to indefiniteness, they may be submitted to the jury for resolution").

FKBP12, inhibited the inflammatory response known to occur after arterial injury and stent implantation, and reduced the smooth muscle cell hyperproliferative response. (A10-A11, ¶25)

II. SUMMARY JUDGMENT OF INVALIDITY CANNOT BE ENTERED FOR THE 1997 PATENTS, BECAUSE BSC'S INVALIDITY ARGUMENTS AGAIN INVOLVE DISPUTED ISSUES OF FACT.

The 1997 patents share a common specification, dating from an April 1997 patent application, which differs from that of the later '662 patent. However, many of the same fundamental factual disputes that arise from BSC's Section 112 arguments involving the '662 patent also arise from BSC's arguments involving the other three patents.

A. BSC's Enablement Arguments Involve Disputed Factual Issues.

1. Based Upon the Teachings of the 1997 Patent Specification, a Person of Ordinary Skill Could Have Identified a Suitable Sirolimus Analog From Among Those That Were Publicly Known.

Like the '662 patent, the 1997 patents are directed to a drug eluting stent containing a combination of previously known elements, including the use of sirolimus and very closely related molecules. The claims of the 1997 patents refer to "rapamycin, or a macrocyclic lactone analog thereof."

None of the 1997 patents concerns the discovery of new sirolimus analogs or their therapeutic use in preventing restenosis. Although more sirolimus analogs had been identified by 2001 than were known in 1997, the evidence shows that at least twenty-five analogs with the same macrocyclic lactone ring as sirolimus, including everolimus, were known as of the filing date of the 1997 patents. (A9, ¶22) As discussed above, there was no need for the inventors to include any figure, diagram, chemical formula, or chemical structure for these analogs, because "a patent need not teach, and preferably omits, what is well known in the art." *Hybritech*, 802 F.2d at 1385. To the extent a person of ordinary skill chose to create a new molecule, the guidance from the patent specification and detailed knowledge of sirolimus's structure,

mechanism of action and binding interactions would have led a person skilled in the art to consider only those with the same macrocyclic ring structure as sirolimus and similar biological activity. (A8-A9, ¶21)

2. After Identifying a Sirolimus Analog, the Person of Ordinary Skill Could Obtain the Analog and Test It Using a Routine Assay.

As with the '662 patent, there is a factual dispute between the parties concerning how a person of skill in the art would go about determining if a known sirolimus analog was suitable for use in the claimed invention. Cordis has presented evidence which shows that by April 1997, a person of ordinary skill would have understood that for a sirolimus analog to have biological activity similar to sirolimus, the analog would need to bind FKBP12 and TOR. (A8, ¶18)

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Tests used to detect a molecule's anti-inflammatory and anti-proliferative properties were also well known as of April 1997. (A11, ¶26) To the extent that BSC disputes this evidence, there is a fact dispute for trial.

3. After Initial Laboratory Testing, the Person of Ordinary Skill Could Have Loaded the Analog on a Stent and Performed Additional Routine Tests.

As noted above, BSC does not appear to dispute the fact that a given sirolimus analog, once identified, could have been incorporated into a stent, using the teachings of the 1997 patents and the knowledge of a person of skill in the art. In any event, if BSC does dispute this fact, there is a further factual dispute, given the declarations of Cordis's experts. (Mikos Decl. at A27-A32, ¶¶27-39; Rogers Decl. at A44-A45, ¶¶24-27)

4. Application of the *Wands* Factors Is Fact-Intensive.

As with the '662 patent, the application of the *Wands* factors to the 1997 patents presents hotly disputed questions of fact. While both sides agree that the skill of those in the art was high, there are factual disputes concerning other *Wands* factors, such as the quantity of experimentation necessary, the amount of direction or guidance presented, the nature of the invention, the state of the prior art, the predictability or unpredictability of the art, and the breadth of the claims. Cordis has presented evidence that sirolimus analogs were known and suitable analogs could have been identified without undue experimentation, thus creating issues of fact for trial. (A9-A11, ¶¶22-27)

B. BSC's Written Description Arguments Involve Disputed Factual Issues.

BSC also argues that the 1997 patents do not satisfy the written description requirement. Again, assuming that a written description requirement exists that is separable from the enablement requirement, its satisfaction is a "question of fact." *Martek*, 2009 WL 2780367 at *3.

Like the later '662 patent, the claims of the 1997 patents use language ("rapamycin, or a macrocyclic lactone analog thereof") that is found in the specification. (*Compare* A1259, Claim 1 *with* A1258, Col. 6, lns. 4-5) The genus of drugs that is encompassed by the claims is tightly limited by reference to a specific structure (the drug must be sirolimus or macrocyclic lactone analog). In addition, the specification provides considerable information on the properties that the drug must have, including a particular effect on cell-cycle progression. (A1258, Col. 5, lns. 38-39; Col. 5, lns. 44-51) Furthermore, there was a known correlation between the structure of sirolimus and the claimed analogs and this biological function (cell-cycle progression would only be inhibited if the drug was structurally able to bind to FKBP12 and then to TOR, thus inhibiting TOR). (A8-A9, ¶21)

Cordis's experts have opined that the information in specification, when combined with the scientific knowledge of the person of ordinary skill, would have been sufficient in 1997 to show that the inventors were in possession of the claimed invention. (Sabatini Decl. at A12-A13, ¶¶28-30; Mikos Decl. at A19-21, ¶¶5-9; Rogers Decl. at A38-39, ¶¶12-13) Identifying specific analogs was unnecessary because at least twenty-five different analogs were already known to the person of ordinary skill, and "an inventor is not required to describe every detail of his invention." *Ven-Tel*, 982 F.2d at 1534.

BSC argues that the inventors "admitted that they never thought their invention included macrocyclic lactone analogs of rapamycin." (D.I. 257 at 8)

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Their "invention" plainly included aspects that were not addressed in laboratory experiments. That is immediately evident from the specification and claims of the 1997 patents, which describe and claim stents containing such analogs.

The written description requirement is satisfied where the specification describes the claimed invention and does so "in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claim invention." *Lockwood*, 107 F.3d at 1572. Whether the inventors actually made and tested a particular embodiment of a given claim is immaterial.

C. BSC's Indefiniteness Argument Is Meritless.

BSC argues that the asserted claims of the 1997 patents are all invalid because the claim term "macrocyclic lactone analog" of rapamycin is indefinite. According to BSC, "macrocyclic lactone analog" should be construed to mean "a macrocyclic lactone molecule with a structure similar to rapamycin." But a person of ordinary skill – given this proposed construction – could make a judgment about whether a given compound had a "structure similar to rapamycin,"

especially in light of the disclosure of the importance of the macrocyclic ring in the specification and the specific properties of sirolimus identified in the specification. (A14, ¶¶32-33)

Further, the claim language here, as with the '662 patent, is at least as precise as the claim language that BSC has used in its own stent patents, which sheds light on what is and is not indefinite. (*See* pp. 27-28)

In any event, for the reasons set forth in the Markman briefs, the Court should adopt the construction proposed by Cordis, which is fully supported by the specification and which lays to rest any possible argument as to whether the claims are indefinite. Under Cordis's proposed construction, "macrocyclic lactone analog" should be construed to mean "a compound structurally similar to sirolimus having the same macrocyclic lactone ring structure which is capable of inhibiting both the inflammatory response known to occur after arterial injury and stent implantation, as well as the smooth muscle cell hyperproliferative response." According to Cordis's expert, Professor Sabatini, a person of ordinary skill could test a given compound, using routine experimental techniques, to determine if it was covered by Cordis's proposed construction. (A10-A11, ¶¶24-27)

If BSC concurs, there is no indefiniteness problem. If BSC disputes Professor Sabatini's analysis, there is a fact dispute underlying the question of indefiniteness, and the fact dispute should be submitted to the jury for resolution.

CONCLUSION

BSC's summary judgment motion should be denied because there are disputed issues of material fact.

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